



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/552,366	10/03/2005	Faramarz Jadihi	GBE0001U\$	8303
23413	7590	03/17/2009	EXAMINER	
CANTOR COLBURN, LLP			SZMAL, BRIAN SCOTT	
20 Church Street			ART UNIT	PAPER NUMBER
22nd Floor			3736	
Hartford, CT 06103				
NOTIFICATION DATE		DELIVERY MODE		
03/17/2009		ELECTRONIC		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

usptopatentmail@cantorcolburn.com

Office Action Summary	Application No. 10/552,366	Applicant(s) JADIDI, FARAMARZ
	Examiner Brian Szmal	Art Unit 3736

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
 - If no period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
 - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 06 January 2009.
 2a) This action is FINAL. 2b) This action is non-final.
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 52-69 is/are pending in the application.
 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
 5) Claim(s) _____ is/are allowed.
 6) Claim(s) 52-69 is/are rejected.
 7) Claim(s) _____ is/are objected to.
 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
 10) The drawing(s) filed on 03 October 2005 is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) Notice of References Cited (PTO-892)
 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
 3) Information Disclosure Statement(s) (PTO-146/08)
 Paper No(s)/Mail Date _____
- 4) Interview Summary (PTO-413)
 Paper No(s)/Mail Date _____
 5) Notice of Informal Patent Application
 6) Other: _____

Claim Objections

1. Claim 68 is objected to because of the following informalities: "a particular said muscle activity" in lines 1-2 should read as "a particular muscle activity". "said apparatus" in line 7, lacks antecedent basis in the claim. "said means for providing signals" in lines 10 and 12 lack antecedent basis. Appropriate correction is required.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 52-69 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claims 52 and 68 both recite the identification of "distinguishing criterion" that differentiates the first reference signal from the second reference signal. However, the specification does not disclose the use of an identification of a "distinguishing criterion" that differentiates the two reference signals from one another.

Claim Rejections - 35 USC § 102

Art Unit: 3736

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 52-59, 62, 63, 65, 67 and 68 are rejected under 35 U.S.C. 102(b) as being anticipated by Ober (4,669,477).

Ober discloses a means for preventing bruxism and further discloses a means for providing signals indicative of muscle activity; a means for processing the signals in order to detect a particular activity; a means for providing a feedback signal; the device is operable in a setup mode and a use mode, the setup mode being distinct from the use mode; in the setup mode the device is user controllable to receive first reference input signals from the providing means which are indicative of other muscle activity and to receive second reference input signals indicative of the particular muscle activity; the device is configured in the setup mode to process the first reference input signals and the second reference input signals to identify therefrom at least one distinguishing criterion which differentiates the first reference input signals from the second reference input signals; in the use mode the device is configured to provide the feedback signal in response to detecting in the signals the at least one distinguishing criterion identified in the setup mode; the device is configured in the setup mode to process the first reference signals and the second reference signals to identify therefrom as the distinguishing criterion at least one frequency in the signals, the amplitude of the signals at which the frequency differentiates the first reference signals from the second

reference signals, and wherein in the use mode, the device is configured to provide feedback in response to detecting at least a predetermined amplitude at the at least one frequency in the setup mode; in the setup mode the device is user controllable to receive the second reference input signals from the providing means which are indicative of an essentially maximal muscle activity; means for registering and storing the signals indicative of muscle activity during a time interval; the device is adaptable by having a means for adjusting the intensity of the feedback; the processing means comprises a means for pattern recognition; the providing means comprises one or more electrodes for sensing EMG signals; the providing means comprises other sensor means; the apparatus comprises means for storing data; a user module for wearing on the head; and a display means for displaying results. See Column 2, lines 30-68; Column 3, lines 1-29 and 60-68; and Column 4, lines 1-4.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. Claim 60 is rejected under 35 U.S.C. 103(a) as being unpatentable over Ober (4,669,477) as applied to claim 52 above, and further in view of Junker et al (6,636,763 B1).

Ober, as discussed above, discloses a means for preventing bruxism but fail to disclose the use of a means of obtaining EEG signals.

Junker et al disclose a brain-body actuated system and further disclose the use of acquiring EEG signals. See Column 3, lines 25-33.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the means of Ober to include the use of EEG, since it is well known in the art that EEG signals can be used to indicate muscle movement.

8. Claim 61 is rejected under 35 U.S.C. 103(a) as being unpatentable over Ober (4,669,477) and Junker et al (6,636,763 B1) as applied to claim 60 above, and further in view of Stice (4,993,423).

Ober and Junker et al, as discussed above, disclose a means of obtaining muscle activity signals but fail to disclose a means for testing the electrodes to determine if the electrodes are connected to the skin properly.

Stice discloses a means for differential lead impedance comparison and further discloses a means for testing the electrodes to determine if the electrodes are connected to the skin properly. See Column 2, lines 64-66.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the combination of Ober and Junker et al to include the ability of determining if the electrodes are contacting the skin, as per the teachings of Stice, since it is well known in the art to utilize a means of determining the contact of the electrodes since it provides a means of accurately acquiring bioelectrical signals from the patient.

9. Claims 64 and 66 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ober (4,669,477) as applied to claim 52 above, and further in view of Sunouchi et al (5,368,043).

Ober, as discussed above, disclose a means for preventing bruxism, but fail to disclose a computer and a means for transferring data thereto; and the apparatus comprises a slave module and a master module, the slave module being designed for wearing by a patient.

Sunouchi et al disclose a means for measuring muscle activity and further disclose a computer and a means for transferring data thereto; and the apparatus comprises a slave module and a master module, the slave module being designed for wearing by a patient. See Column 6, lines 65-68; and Column 9, lines 18-27.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the means of Ober to include the use of a computer, as per the teachings of Sunouchi et al, since it would provide an external processing means to process the data and control the feedback means.

10. Claim 69 is rejected under 35 U.S.C. 103(a) as being unpatentable over Ober (4,669,477) as applied to claim 56 above, and further in view of Prass (6,306,100 B1).

Ober, as discussed above, disclose a means for treating bruxism, but fail to teach the stored signals indicative of muscle activity are processed by FFT analysis.

Prass discloses a means for neurophysiological monitoring and further disclose the stored signals indicative of muscle activity are processed by FFT analysis. See Column 37, lines 52-59.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the means of Ober, to include the use of FFT analysis on the stored EMG signals, as per the teachings of Prass, since it would provide a means for performing frequency analysis on the acquired EMG signals.

Response to Arguments

11. Applicant's arguments filed January 6, 2009 have been fully considered but they are not persuasive.

The Applicants argue the current specification does provide support for the claimed identification of "at least one distinguishing criterion", by providing page 13, lines 14-18 as evidence for said support. The Examiner respectfully disagrees. Page 13, lines 14-18 in the current specification do not provide any support for an identification of at least one distinguishing criterion that differentiates the first reference input signals from the second reference input signals. The cited section only provides support for registering the maximal level of activity as well as normally occurring muscle activities, which may be utilized for establishing criteria for providing a feedback. Nowhere in this cited section, nor in the rest of the current specification, does it teach an identification of at least one distinguishing criterion. Therefore, the current rejection is being maintained.

12. In response to applicant's argument that Ober fails to teach an apparatus that is operable in a set-up mode and in a use mode, wherein the set-up mode is controllable to receive first and second reference input signals, a recitation of the intended use of the claimed invention must result in a structural difference between the claimed

invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim.

The Applicants argue the Examiner's interpretation of Ober in the Office Action mailed on October 14, 2008 "goes beyond any reasonable interpretation of Ober", with respect to Ober inherently teaching a set-up mode because one would not adjust the threshold during sleep. The Examiner respectfully disagrees. The disclosure of Ober discloses a means for treating bruxism that comprises EMG electrodes, a comparator for comparing incoming signals to a predetermined threshold, a memory for recording the number of times feedback was given to the patient, and a stimulator for providing feedback to the user based on a predetermined threshold. The threshold of the device can be adjusted through the use of threshold adjustment member (32). One of ordinary skill in the art would recognize the fact that a proper threshold adjustment can only occur during an office visit while the patient is awake, so the office practitioner can properly adjust the device. The threshold adjustment would also clearly occur during a "set-up mode" utilizing multiple input signals. One of ordinary skill in the art would not set-up a device utilizing only a single input signal, because the device would have a threshold based on a single signal, which would cause the threshold to be improperly set too high, resulting in no feedback when bruxism occurs, or too low, resulting in feedback being applied to the patient when bruxism is not occurring.

13. In response to applicant's argument that Ober does not teach the apparatus is configured in the set-up mode to process the first reference signals and the second

reference signals to identify a criterion that differentiates the first reference input signals from the second reference input signals, a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim.

14. In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., an automatic determination of a threshold value) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). Current Claims 52 and 68 only claim a means for setting up the device to provide a threshold, acquiring EMG signals, processing the signals, providing a feedback to the user in response to a signal being above a threshold. The current claims do not disclose an automatic determination of a threshold by the device.

15. In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., a comparison of the first reference signals and the second reference signals) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). The current claim language of Claims 52 and 68 only state the first and second reference signals are

processed to identify a criterion therefrom. The claims fail to state the first and second reference signals are compared to one another.

16. The Applicants also argue Ober fails to teach the claimed elements of Claim 56. The Examiner respectfully disagrees. In Column 3, lines 63-64, Ober clearly discloses the recorder can be interfaced with the control circuit; the circuit that processes incoming EMG signals and compares them to a threshold. If the recorder is interfaced with the control circuit, the recorder will be capable of recording EMG signals over time, as well as recording the number of stimulation pulses given to the patient during sleep.

Conclusion

17. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian Szmal whose telephone number is (571)272-4733. The examiner can normally be reached on Monday-Friday, with second Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (571) 272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Brian Szmal/
Examiner, Art Unit 3736

/Max Hindenburg/
Supervisory Patent Examiner, Art Unit 3736